1631

Serial No.: 09/854,093 **Docket No.: PF-0357-1 DIV**

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: **Box Non-Fee Amendment,** Commissioner for Patents, Washington, D.C. 20231 on April 9, 2003.

By: _____ Printed: D. Ellis

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Lal et al.

Title: NEW SYNAPTOJANIN ISOFORM

Serial No.: 09/854,093 Filing Date: May 10, 2001

Examiner: Sheinberg, M. Group Art Unit: 1631

Box Non-Fee Amendment
Commissioner for Patents
Washington, D.C. 20231

TRANSMITTAL FEE SHEET

Sir:

Transmitted herewith are the following for the above-identified application:

1. Return Receipt Postcard; and
2. Response to Restriction Requirement (7 pp.).

The fee has been calculated as shown below.

Claims	Claims After Amendment	-	Claims Previously Paid For	=	Present Extra	Other Than Small Entity Rate	Fee		Additional Fee(s)
Total	19	-	20		0	x$18.00	0	$	0
Indept.	3	-	3		0	x$84.00	0	$	0
First Presentation of Multiple Dependent Claims						+280.00	0	$	0
							Total Fee:	$	0

X No additional Fee is required.

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17, or credit overpayment to Deposit Account No. 09-0108. **A duplicate copy of this sheet is enclosed.**

Respectfully submitted,

INCYTE CORPORATION

Date: April 9, 2003

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In re Application of:	Lal et al.		
Title:	NEW SYNAPTOJANIN ISOFORM		
Serial No.:	09/854,093	Filing Date:	May 10, 2001
Examiner:	Sheinberg, M.	Group Art Unit:	1634

Box Non-Fee Amendment
Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO RESTRICTION REQUIREMENT UNDER 35 U.S.C. 121

Sir:

This paper is responsive to the Restriction Requirement and Request for Election dated March 17, 2003, setting a one (1) month term for response. Prior to examination of the application, please amend the specification of the above-identified application as listed below.

CLAIM AMENDMENTS

Please cancel claims 11-14 without prejudice.

Please add new claims 35-37 as follows.

1. (Original) An isolated polypeptide comprising an amino acid sequence selected from the group consisting of:

a) an amino acid sequence of SEQ ID NO:1,

b) a naturally occurring amino acid sequence having at least 95% sequence identity to an amino acid sequence of SEQ ID NO:1,

c) a biologically active fragment of an amino acid sequence of SEQ ID NO:1, and

d) an immunogenic fragment of an amino acid sequence of SEQ ID NO:1.

2. (Original) An isolated polypeptide of claim 1, having a sequence of SEQ ID NO:1.

3. (Original) A composition comprising an effective amount of a polypeptide of claim 1 and an acceptable excipient.

4. (Original) A composition of claim 3, wherein the polypeptide has the sequence of SEQ ID NO:1.

5. (Original) An isolated polynucleotide encoding a polypeptide of claim 1.

6. (Original) A recombinant polynucleotide comprising a promoter sequence operably linked to a polynucleotide of claim 5.

7. (Original) A cell transformed with a recombinant polynucleotide of claim 6.

8. (Original) A method for producing a polypeptide of claim 1, the method comprising:

a) culturing a cell under conditions suitable for expression of the polypeptide, wherein said cell is transformed with a recombinant polynucleotide, and said recombinant polynucleotide comprises a promoter sequence operably linked to a polynucleotide encoding the polypeptide of claim 1, and

b) recovering the polypeptide so expressed.

9. (Original) An isolated antibody which specifically binds to a polypeptide of claim 1.

10. (Original) An isolated polynucleotide comprising a polynucleotide sequence selected from the group consisting of:

a) a polynucleotide sequence of SEQ ID NO:2,

b) a naturally occurring polynucleotide sequence having at least 95% sequence identity to a polynucleotide sequence of SEQ ID NO:2,

c) a polynucleotide sequence complementary to a),

d) a polynucleotide sequence complementary to b), and

e) an RNA equivalent of a)-d).

11.-14. (Canceled)

15. (Original) A method for screening a compound for effectiveness as an agonist of a polypeptide of claim 1, the method comprising:

a) exposing a sample comprising a polypeptide of claim 1 to a compound, and

b) detecting agonist activity in the sample.

16. (Original) A method for screening a compound for effectiveness as an antagonist of a polypeptide of claim 1, the method comprising:

a) exposing a sample comprising a polypeptide of claim 1 to a compound, and

b) detecting antagonist activity in the sample.

17. (Original) A method for screening a compound for effectiveness in altering expression of a target polynucleotide, wherein said target polynucleotide comprises a polynucleotide sequence of SEQ ID NO:2, the method comprising:

a) exposing a sample comprising the target polynucleotide to a compound, under conditions suitable for the expression of the target polynucleotide,

b) detecting altered expression of the target polynucleotide, and

c) comparing the expression of the target polynucleotide in the presence of varying amounts of the compound and in the absence of the compound.

18. (Original) A method for assessing toxicity of a test compound, said method comprising:

a) treating a biological sample containing nucleic acids with the test compound,

b) hybridizing the nucleic acids of the treated biological sample with a probe comprising at least 20 contiguous nucleotides of a polynucleotide of claim 10 under conditions whereby a specific hybridization complex is formed between said probe and a target polynucleotide in the biological sample, said target polynucleotide comprising a polynucleotide sequence of a polynucleotide of claim 8 or fragment thereof,

c) quantifying the amount of hybridization complex; and

d) comparing the amount of hybridization complex in the treated biological sample with the amount of hybridization complex in an untreated biological sample, wherein a difference in the amount of hybridization complex in the treated biological sample is indicative of toxicity of the test compound.

19. (Original) A diagnostic test for a condition or disease associated with the expression of NSYN-1 in a biological sample comprising the steps of:

a) combining the biological sample with an antibody of claim 9, under conditions suitable for the antibody to bind the polypeptide and form an antibody: polypeptide complex, and

b) detecting the complex, wherein the presence of the complex correlates with the presence of the polypeptide in the biological sample.

20. (Original) The antibody of claim 9, wherein the antibody is:

a) a chimeric antibody,

b) a single chain antibody,

c) a Fab fragment,

d) a $F(ab')_2$ fragment,

e) a Fv fragment, or

f) a humanized antibody.

21.-34. (Canceled)

35. (New) A method of screening for a compound that specifically binds to the polypeptide of claim 1, the method comprising:

a) combining the polypeptide of claim 1 with at least one test compound under suitable conditions, and

b) detecting binding of the polypeptide of claim 1 to the test compound, thereby identifying a compound that specifically binds to the polypeptide of claim 1

36. (New) A method of making a polyclonal antibody, the method comprising:

a) immunizing an animal with the polypeptide of claim 2, or an immunogenic fragment thereof, under conditions to elicit an antibody response,

b) isolating antibodies from said animal, and

c) screening the isolated antibodies with the polypeptide, thereby identifying a polyclonal antibody which binds specifically to a polypeptide comprising an amino acid sequence of SEQ ID NO:1.

37. (New) A method of making a monoclonal antibody, the method comprising:

a) immunizing an animal with the polypeptide of claim 2, or an immunogenic fragment thereof, under conditions to elicit an antibody response,

b) isolating antibody producing cells from the animal,

c) fusing the antibody producing cells with immortalized cells to form monoclonal antibody-producing hybridoma cells,

d) culturing the hybridoma cells, and

e) isolating from the culture monoclonal antibody which binds specifically to a polypeptide comprising an amino acid sequence of SEQ ID NO:1.

REMARKS

Claims 11-14 have been canceled without prejudice, and new claims 35-37 have been added to claims additional methods of use of the polypeptides of the invention. Support for new claims 35-37 is found throughout the specification, for example, for new claim 35 at p. 40, line 21 throughout p. 41, line 4 (compound screening), and for new claims 36-37 at p. 26, line 10 through p. 28, line 2, and at p. 48, Example IX (antibody production). No new matter is added by any of these amendments, and entry of the amendments is requested.

Restriction Requirement

In the Restriction Requirement, the Examiner requested Applicants to elect one of the following inventions:

Group I (claims 1-4) drawn to polypeptides.

Group II (claims 5-7, 10 and 11) drawn to polynucleotides and compositions containing same.

Group III (claim 8) drawn to methods of expression of polypeptides.

Group IV (claims 9, 19 and 20) drawn to an antibody.

Group V (claims 12 and 13) drawn to a method of detecting a nucleic acid by hybridization.

Group VI (claim 14) drawn to a method of detecting nucleic acid by polymerase chain reaction.

Group VII (claim 15) drawn to a method of screening and detecting an agonist using a polypeptide.

Group VIII (claim 16) drawn to a method of screening and detecting an agonist (sic, antagonist) using a polypeptide.

Group IX (claim 17) drawn to a method of screening compounds that alter expression of a nucleic acid.

Group X (claim 18) drawn to a method of testing compound toxicity.

Applicants hereby elect, with traverse, to prosecute Group I, which includes and is drawn to Claims 1-4. Applicants object to the excessive restriction of claims, particularly with regard to compositions of matter and their methods of use. Method of use claims 8, 15 and 16 depend from, and are of the same scope as their respective composition of matter claims, e.g., claim 1. These claims could therefore be examined together without an undue burden of search. It is noted, for example, that claims 15 and 16 are classified and subclassifed identically yet are restricted into separate groups. It is further noted that the Examiner has agreed to examine antibody claims together with their methods of use. See Group IV, claims 9, 19 and 20.

Applicants therefore request reconsideration of the Restriction Requirement and examination of claims 1-4, 8, 15 and 16 of Groups I, III, VII and VIII, as well as new claims 35-37. In the event the

Examiner maintains the Restriction Requirement, Applicants reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications.

CONCLUSION

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108.

Respectfully submitted,

INCYTE CORPORATION

Date: April 9, 2003

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